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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,377	01/26/2005	Caroline Garey	P08555US00/BAS	7987
881 7590 10/16/2007 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			EXAMINER GABEL, GAILENE	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 10/16/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/522,377		GAREY ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Gailene R. Gabel		1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Preliminary Amendment Entry***

1. Applicant's preliminary amendment filed January 26, 2005 is acknowledged and has been entered. Claims 16 and 17 have been cancelled. Claims 5 and 9-13 have been amended. Accordingly, claims 1-15 are pending and are under examination.
2. Examiner appreciates Applicant's notification to the Office of the submission of preliminary amended set of claims.

### ***Priority***

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Specification***

#### **Content of Specification**

4. Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f).

As to the brief description of the drawings:

- Figure 4A and Figure 4B are not differentially described in the specification.
- Figure 5A and Figure 5B are not differentially described in the specification.
- Figure 7A and Figure 7B are not differentially described in the specification.
- Figure 9A and Figure 9B are not differentially described in the specification.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, part a) is indefinite in reciting, "identification means for identification thereof" because it is unclear what the identifications means intends to identify, i.e. the identification means or the primary support. Does Applicant intend, "identification means for identification of the primary support."

Claim 1, part d) is indefinite in reciting, "identification means for identification thereof" because it is unclear what the identifications means intends to identify, i.e. the identification means or the secondary support. Does Applicant intend, "identification means for identification of the secondary support."

Claim 1, part e) is ambiguous in reciting, "post-reaction interaction" because it is unclear what Applicant intends to encompass in the recitation of "post-reaction". Does Applicant perhaps intend a, "binding interaction" between the primary analytes and the secondary analytes. Please clarify.

Claim 1, part e) is also ambiguous in reciting, "detecting the identification means" because it is unclear how the identification means is detected differentially between unreacted analytes bound to primary and secondary supports and reacted analytes

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bound to primary and secondary supports. Is there a change in signal effected upon the identification means for each one of the primary and secondary supports if an interaction between the primary analytes and the secondary analytes were to occur.

Please clarify.

Claim 1 is indefinite for being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. In this case, it is unclear what structural cooperative relationship exists between each one of the recited components of the claimed system so as to allow multiparameter analysis of the analytes as required by the preamble.

Claims 2-14 have improper antecedent basis problems in reciting, "A system according to claim...". Perhaps, Applicant intends, "The system according to claim..." for proper antecedent basis.

Regarding claim 9, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 11, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 12 is ambiguous and lacks clear antecedent basis for the recitation of, "wherein the primary and secondary supports are only partially covered in their respective primary or secondary analyte" because claim 1 from which it depends in part

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a) and part d) only recite, "at least one primary analyte is bound to each primary support" and "at least one secondary analyte is bound to each secondary support", respectively. Accordingly, it is unclear how claim 12 appears to imply "full" coverage of the primary and secondary supports with their respective analytes. Additionally, the term "only partially" in claim 12 is a relative term which renders the claim indefinite because the term "only partially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 14 is vague and indefinite in reciting "the liquid suspension is accommodated on a solid substrate" because it is unclear what is encompassed in the term "accommodated" as used in the claim, especially with respect to the liquid suspension. Does Applicant perhaps intend, "... contacted with a solid substrate" or "... contained in" or "... dispensed into" or "...disposed into."

Claim 14 is indefinite in reciting, "which substrate includes..." because it is unclear what other elements are further included with the substrate. Perhaps Applicant intends, "which substrate comprises..."

Claim 14 is vague and indefinite in relation to claim 1 from which it depends, for being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. In this case, it is unclear what structural cooperative relationship exists between each one of the recited components in claim 14 and the components

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recited in the claimed system of claim 1, so as to allow multiparameter analysis of the analytes as required by the preamble.

Claim 15 is non-idiomatic and therefore confusing, in reciting "the method including the steps of" because it is unclear what other elements are further included in the claim. Perhaps, Applicant intends, "the method comprising."

Claim 15, step a) is indefinite in reciting, "identification means for identification thereof" because it is unclear what the identification means intends to identify, i.e. the identification means or the primary support. Does Applicant intend, "identification means for identification of the primary support."

Claim 15, step e) is indefinite in reciting, "identification means for identification thereof" because it is unclear what the identification means intends to identify, i.e. the identification means or the secondary support. Does Applicant intend, "identification means for identification of the secondary support."

Claim 15, step h) is ambiguous in reciting, "post-reaction interaction" because it is unclear what Applicant intends to encompass in the recitation of "post-reaction". Does Applicant perhaps intend a, "binding interaction" between the primary analytes and the secondary analytes. Please clarify.

Claim 15, step h) is also ambiguous in reciting, "detecting the identification means" because it is unclear how the identification means is detected differentially between unreacted analytes bound to primary and secondary supports and reacted analytes bound to primary and secondary supports. Is there a change in signal effected upon the identification means for each one of the primary and secondary supports if an

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interaction between the primary analytes and the secondary analytes were to occur.

Please clarify.

Claim 15 is indefinite for being incomplete for omitting essential structural and functional cooperative relationships of elements as well as essential method steps, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. In this case, it is unclear what structural and functional cooperative relationship exists between each one of the recited components of the claimed system so as to enable multiparametric analysis of the analytes in a method, as required by the preamble.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-9 and 11-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Singh et al. (US 2002/0034827).

Singh et al. disclose a system for use in a method of multiparameter analysis of analytes, comprising of primary supports having a primary probes (i.e. "analyte") attached thereto, secondary supports having secondary probes attached thereto (Figure



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1; page 4 [0037]; and page 8 [0067]). These solid supports are derivatized fibers having probes attached thereto, that form differentially encoded extraction probes which are capable of binding specific analytes that are specific for the corresponding probe (page 9 [0073] and the Table therein). The dimensions of the different supports are in the range of 100  $\mu\text{m}$  or preferably less than 1  $\mu\text{m}$  (i.e. less than 300  $\mu\text{m}$  in claim 2, less than 150  $\mu\text{m}$  in claim 3, less than 50  $\mu\text{m}$  in claim 4, less than 100  $\mu\text{m}$  in claim 6, less than 50  $\mu\text{m}$  in claim 7, less than 10  $\mu\text{m}$  in claim 8) (page 4 [0040-0041] and page 11 [0095]). The solid supports may be partially or totally coated (i.e. covered) with probes (page 4 [0038]). Each one of the supports comprise of identification means (identification tags) which vary according to composition and/or length of the rods (Nanobarcodes). The supports are differentiable by distinguishing geometrical features including size: length and width, shape, and composition and are encoded with a barcode (page 9 [0076]). The supports are suspended in liquid solution which makes the supports compatible for use in solution-based multiparameter (multiplexed) assays. In accordance, the system is interfaced (i.e. in communication with) with a measuring means for detecting and analyzing interaction between the probe and analytes (page 4 [0028]; page 5 [0045]; page 6 [0050]; and page 9 [0077]). The identification means may further be incorporated with fluorescent tags so as to allow optical identification of interactions in detection mechanisms (page 13 [0112]). The liquid suspension upon which the system is suspended, may also be dispensed into a solid substrate that is further coated in fixedly arranged probes, so as to be configured in an array that can readily be identified by positional (spatial) address of the fiber (i.e. positional

identification) (page 4 [0041]). Accordingly, Singh et al. is deemed to anticipate the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al. (US 2002/0034827) in view of Mandecki (US Patent 6,361,950).

Singh et al. is discussed supra. Singh et al. differs from the instant invention in failing to disclose that the identification means is a radio frequency identification transponder.

Mandecki discloses using solid supports having attached thereto probes or binding ligands for use in multiplexed assays, and wherein each one of the solid supports is further associated with a radio frequency identification transponder (RFID) so that data concerning the multiplexed assays are encoded into the transponders (Abstract and column 4, lines 47-60). Advantage of transponder scanner systems is that two units are not electrically connected by wire but are coupled inductively by use of electromagnetic radiation. Most importantly the narrow focus of beam of a laser light enable only one transponder to be active at a time during decoding step, hence, significantly reducing noise level (column 1 line 56 to column 2, line 2 and column 6, lines 23-50).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute RFID as taught by Mandecki into the multiplexed analytical system as taught by Singh as an identification means, because RFID scanner systems have the advantage of reducing noise levels when measuring specific interactions between probes and analytes, which can add accuracy into the multiparametric method of detecting analytes as taught by Singh.

8. No claims are allowed.

**Remarks**

9. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

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Dames et al. (WO 00/16893) disclose systems for parallel multiparametric bioassays comprising of different microfabricated labels having a surface label of anodized metal (primary supports having a primary analyte attached thereto, secondary supports having secondary analytes attached thereto and identification means incorporated therein). See Abstract; Figure 1; Figure 2; and pages 3 and 4.

Bruchez et al. (US 2001/0034034) disclose systems for multiparameter analysis of analytes comprising nanoparticles or quantum dots or semiconductor nanocrystals (primary supports having a primary analyte attached thereto, a secondary supports having secondary analytes attached thereto, and a measuring means arranged to detect interaction between the analytes). The system is suspended in fluid or liquid solution. See Figure 1A; Figure 1B; Figure 5; page 8, [0100-0101] and pages 13-16.

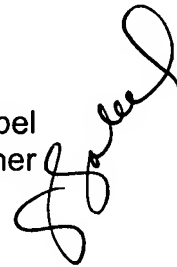
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gailene R. Gabel  
Primary Examiner  
Art Unit 1641



October 12, 2007